UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM **April 8, 2021**

Subject: Section 18 Risk Assessment for BIAXAM™ Film for Proposed Use in Minnesota, Utah, and Georgia

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Decision No.: 569156	Registration Number: NA
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Risk Assess Type: NA	Case No(s):
TXR No.: NA	CAS No(s): 1637665-77-0
MRID No(s).: NA	40 CFR:

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Inert ingredient information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

1.0 Introduction

The Minnesota Department of Agriculture (MDA), the Utah Department of Agriculture and Food (UDAF), and the Georgia Department of Agriculture have requested a Public Health Emergency Exemption under the provisions of Section 18 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, for the use of a new active ingredient (a polymer formulated as BIAXAM™ film) to provide ongoing, residual protection against SARS-CoV-2, the virus that causes COVID-19. The product is proposed to be used on indoor, hard, non-porous, non-food contact surfaces in airport terminals and airplanes owned or controlled by Delta Air Lines, Inc. in the states of Minnesota, Utah, and Georgia.

2.0 Proposed Product and Use Pattern

The proposed end-use product, BIAXAM film, is a transparent peel-and-stick film consisting of a layer of a BIAXAM polymer [redacted]
This film is applied to surfaces in Delta-owned or -controlled airport terminals and airplanes. Surfaces in airport terminals include but are not limited to: counters (*e.g.*, check-in counters), kiosks, door handles, elevator buttons, plastic luggage bins, terminal and bridge handrails, terminal shuttle bus and train hand rails, grab bars, clear exposure-limiting divider walls, seating surfaces, computer mice and keyboards, and luggage carousel surfaces. Surfaces in airplanes include but are not limited to countertops, solid surface arm rests, solid seating surfaces, seatbelts, door handles, overhead bin handles, overhead luggage bins, seat-back entertainment screens, and overhead fixtures (air conditioning and lighting buttons).

The inert platform is either [redacted]

2.1 Chemistry of the BIAXAM Polymer Used in the BIAXAM Film

The BIAXAM polymer, also known as benzene, 1-(1,1-dimethylethyl)-4-ethenyl-, polymer with ethenylbenzene and 2-methyl-1,3-butadiene, sulfonated (CAS No. 1637665-77-0), is a new sulfonated polymer active ingredient (a.i.). It contains [redacted] that provide antimicrobial, flexibility, and strength (durability) properties, respectively. [redacted]

[redacted]

3.0 Human Health Risk Assessment

Although dermal exposure to the BIAXAM film is possible, the BIAXAM polymer has a high molecular weight [redacted] and is not expected to be readily absorbed through the cell membranes of living organisms. Inhalation, incidental oral and dietary exposures to the BIAXAM polymer are not expected from the proposed uses and thus are not quantitatively assessed.

The [redacted]on the BIAXAM polymer is very thin and could only come into dermal contact with the stratum corneum, the 10- to 30-µm thick outermost layer of epidermis, consisting of approximately 20 layers of dead skin cells, compared to the 0.1-µm-thick proton-rich

environment of the hydrated BIAXAM polymer surface. Because the skin is not ionically charged and not expected to promote exchange of the protons localized on the BIAXAM polymer surface, any scenarios resulting in dermal exposure to the [redacted] are expected to result in minimal dermal loading and be insufficient to cause a negative effect on the skin. Similarly, because the [redacted] residue transfer to the skin is not expected.

The registrant submitted a dermal irritation study and a dermal sensitization study (Novak *et al.*, 2020). The dermal irritation study was performed in 2011 using an *in vitro* reconstructed human epidermal model with the polymer material from Kraton as the test article. The results from the *in vitro* dermal irritation study showed that the test article did not induce dermal irritation. The dermal sensitization study was performed in guinea pigs in 2011, and the results showed that the chemical used did not induce dermal sensitization after challenge. Based on the results from these two dermal studies and the minimal dermal loading expected following exposure, risks are not expected and a quantitative dermal exposure risk assessment for the proposed product/use is not needed and was not conducted.

4.0 Environmental Risk Assessment

Based on the proposed indoor uses and low toxicity of the BIAXAM polymer, risks to terrestrial and aquatic non-target organisms are not expected. No environmental fate information is available for the BIAXAM polymer (CAS No. 1637665-77-0); based on its chemical structure [redacted] it is not expected to undergo hydrolysis, photolysis, or biodegradation in the environment. Environmental exposure to the BIAXAM polymer is not expected because of its use patterns (indoor uses only), [redacted] to the immediate polymer surface, and lack of bioavailability to organisms (due to large molecular size and resulting inability to be absorbed through cell membranes). Furthermore, an acute aquatic toxicity study on rainbow trout (*Oncorhynchus mykiss*) demonstrated a 96-hr No-Observed-Effect-Concentration (NOEC) of 1,000 mg/L, indicating the BIAXAM polymer is not expected to be toxic to aquatic life (Rebstock, 2012). The study was conducted on MD9210, a polymer that is substantially similar to the BIAXAM polymer but with a higher degree of sulfonation and thus higher ion exchange capacity or sulfonic acid functionality (representative of a worst-case scenario).

Based on the lack of exposure to non-target terrestrial and aquatic organisms, and low toxicity from the BIAXAM polymer to aquatic receptors, the Agency has made a "no effects" determination for the BIAXAM polymer under the Endangered Species Act (ESA) for all listed species and designated critical habitats for such species.

5.0 Conclusions

Due to the limited exposure potential of the BIAXAM polymer based on its large molecular size, low toxicity, and [redacted] risks to humans and nontarget organisms are not expected from the proposed uses.

6.0 References

Kraton. (2021a). Antiviral Mechanism and its Significance to Safety. Presented to EPA on January 22, 2021.

Kraton. (2021b). Response to Questions submitted by the EPA on Jan 29, 2021. Submitted to EPA on February 5, 2021.

Novak, M.T., Gustafson, J.B., and Harney, M.B. (2020). Discussion of Risk Information. Utah Department of Agriculture and Food (UDAF). 109p.

Rebstock, M. (2012). MD 9210: Acute Toxicity of the Water Accommodated Fraction (WAF) to the Rainbow Trout, *Oncorhynchus mykiss*, Determined Under Static Test Conditions. ABC Study No. 68874. ABC Laboratories, Inc. 31 p.